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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,338	08/01/2005	Ulrike G Munderloh	09531-125US1	6945
26191 7590 07/26/2007 FISH & RICHARDSON P.C. PO BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER MAASHO, KERIMA K	
			ART UNIT 1645	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/524,338

Applicant(s)

MUNDERLOH, ULRIKE G

Examiner

Kerima Maasho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 3-8, 11-17, 19, 23, 25, 30, 33, 34, 36, 39, 44 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 9, 10, 18, 20-22, 24, 26, 27, 31, 32, 37, 38, 40-43, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 29 and 35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 07/12/2006, 10/19/2006.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

***Detailed action***

Applicant's election with traverse; the species of vero cells with regards to mammalian cells, *A. marginale* with regards to Anaplasma and tick cells with regards to the origin of *A. marginale*; in the reply filed on 06/18/2007 is acknowledged. The traversal is on the ground(s) that the restrictions of the claims are improper under PCT rule 13.1 and 13.2. This is not found persuasive because the species as claimed do not relate to a single general inventive concept as they relate to species each pose mutually exclusive properties and therefore have distinct special technical features for reasons stated in the original requirement for species election. The requirement is still deemed proper and is therefore maintained.

Applicants election of species read on claims 1, 2, 9, 10, 18, 20, 21, 22, 24, 26-29, 31, 32, 35, 37, 38, 40-43, 45 and 46 (please note that claims 7 and 16 as applicant filed in their reply on 06/18/2007 read on unelected species of endothelial cells, claims 35 and 37 that read on *A. marginale* and vero cells have been included by the examiner as they relate to the elected species. Claims 3-8, 11-17, 19, 23, 25, 30, 33-34, 36, 39, 44 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-47 are pending in this application, however, only the elected group of claims 1, 2, 9, 10, 18, 20, 21, 22, 24, 26-29, 31, 32, 35, 37, 38, 40-43, 45 and 46 are under consideration in this examination.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph rejections***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 40-43, 45 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-43, 45 and 46 recite a method of obtaining an Anaplasma species comprising isolation from the mammalian cells, but do not set forth any steps involved in the method/process for isolating the microorganism from the cells. For this reason it is unclear what method/process applicant is intending to encompass, this is not defined in the preamble. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Is Anaplasma released into the culture medium from the infected cells in an active process by the organism without any intervention by the inventor? or is it obtained by lysing the cells so that the organism is released into the medium? The metes and bounds of the claimed method are not clear. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 42 and 45 also recite an attenuated Anaplasma species this is vague as there is no specific definition for the attenuation specified in the preamble. As stated in the specification attenuation can be performed by heat-exposure, chemical inactivation,

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or by subjecting the culture through several passages until the organism has lost its infective ability.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

In the instant invention claims 1, 2, 9, 10, 18, refer to an isolated mammalian cell stably infected with *Anaplasma marginale*; claims 20, 21, 22, 24, refer to a method of making a mammalian cell that is stably infected with *A. marginale*; claims 26-29, 31, 32, 35, 37, 38, refer to a method of propagating *A. marginale* from stably infected nucleated mammalian cell; claims 40-43, 45 and 46 refer to a method for obtaining *A. marginale* from stably infected nucleated mammalian cell.

2. Claims 1, 2, 9, 10, 18, 20, 21, 22, 24, 26-27, 31, 32, 37, 38, are rejected under 35 U.S.C. 102 (b) as being anticipated by Waghele et al (Vet Parasitol 1997, vol 73, pp 43-52, filed in the IDS).

Waghela et al teach a continuous in vitro culture of *A. marginale* in bovine erythrocytes co-cultured with endothelial cells, Co-culture of the infected erythrocytes with endothelial cell monolayers allowed for longer maintenance with a parasitemia ranging from 5-13% through four passages over 16 weeks (see abstract and p 50). Waghela et al also teach the propagation of *A. marginale* in the erythrocytes co-cultured with the endothelial cells (see p 47). Waghela et al teach a method of making and propagating mammalian cells with *A. marginale* to produce a continuous culture of *Anaplasma* (see p 44). Waghela et al's teaching anticipates the mammalian nucleated cells of the instant claim 1, 2, 9, 10 and 18 as well as the method of making and propagating *Anaplasma* infection in the cells of the instant claims 26, 27, 31, 32, 37, and 38.

3. Claims 1, 2, 9, 10, and 18, 40-43 and 45-46 are rejected under 35 U.S.C. 102 (b) as being anticipated by Blouin et al (Revue Elev Med vet Pays trop 1993, vol 46, pp 49-56, filed in the IDS).

Blouin et al teach a method for establishing persistence of tick-derived *A. marginale* in cultured bovine turbinate and endothelial cells (see p 49). Blouin et al further teach the use of mammalian cell persistently infected with *A. marginale* to inoculate susceptible calves this was done by isolating the *Anaplasma* from the infected mammalian cells. Since attenuation could be brought about by several passages wherein the organism loses its infectivity, Blouin et al's teaching meets the limitations of claims 42 and 45 in the instant invention, because the calves that were inoculated with bovine turbinate

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culture material did not develop clinical Anaplasmosis. The turbinate and endothelial cells are adherent and nucleated mammalian cells, therefore Blouin et al's teaching anticipates the above claims.

4. Claims 20-22, 24, 26-28, 31, 32, 37 and 38 are rejected under 35 U.S.C. 102.(b) as being anticipated by Marble (US Patent 3,616,202, filed in the IDS).

Marble teaches a method for culturing *A. marginale* in rabbit bone marrow that meets the mammalian nucleated and adherent cells of the instant claims 20-22, 24, 26 (see column 1, lines 20-27). Bone marrow cells are known to comprise of nucleated and adherent cells as well as a lot of normoblasts (immature erythrocytes with a nucleus) since Marble is using cells that are flushed out from the marrow without isolating a particular cell type it reads on both the nucleated and adherent cells of the instant inventions. Marble also teaches the inoculum used to contact or seed the mammalian cells may be derived from any cellular material infected with *A. marginale* which anticipates the tick cells of claim 28 of the instant invention (see column 2, lines 21-22). Marble further teaches a continuous culture system wherein *A. marginale* is maintained in the bone marrow culture by weekly passages that retained its infectivity even after 140 days (20 passages) (see column 2, lines 29-33). Therefore, Marble's teaching of making and propagating *A. marginale* by contacting nucleated mammalian cells with *A. marginale* obtained from infected cellular material anticipates the instant claims 20-22, 24, 26-28, 31, 32, 37 and 38.

***Conclusion***

Claims 1, 2, 9, 10, 18, 20, 21, 22, 24, 26-29, 31, 32, 35, 37, 38, 40-43, 45 and 46 are rejected as explained above.

***Allowable Subject Matter***

The extensive search did not result in prior art for the use of vero cells as the mammalian cells infected with *A. marginale* (claims 29 and 35).

Claims 29 and 35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kerima Maasho whose telephone number is 571-270-3055. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer Graser/

Primary Examiner, Art Unit 1645